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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,207	06/22/2001	Wilfred A. Keller	S&B-C100	5571

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EXAMINER

FOX, DAVID T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 08/27/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/886,207

Applicant(s)

KELLER ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-70, 72-74, 76, 80-84, 88-92 and 96-110 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 99 is/are allowed.
- 6) ☒ Claim(s) 59-66, 69-70, 72-74, 76, 80-82, 88, 92, 96-98, 100-106, 109-110 is/are rejected.
- 7) ☒ Claim(s) 67, 68, 83, 84, 89-91, 107 and 108 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendments of 17 June 2003 have overcome the following rejections: indefiniteness rejections, written description and scope of enablement rejections regarding cold-inducible promoters or non-*Agrobacterium* oncogene 2, anticipation rejections, and obviousness rejection over Dotson et al alone.

Claims 59-70, 72-74, 76, 80-84, 88-92 and 96-110 are pending. All claims drawn to non-elected inventions have been cancelled.

Claims 59-66, 69-70, 72-74, 76 and 80-82 remain, and new claims 100-106 and 109-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, regarding non-exemplified conditionally lethal genes, as stated on pages 3-6 of the last Office action.

Claims 59-66, 69-70, 72-74, 76, and 80-82 remain, and new claims 100-106 and 109-110 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to genetic constructs comprising an iamH gene and methods of their use to transform plants, does not reasonably provide enablement for claims broadly drawn to any conditionally lethal gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action on pages 6-8.

Claims 59, 61-64, 66, 69-70, 72-74, 76 and 80-82 (amended) and new claims 101-104, 106 and 109-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dotson et al (U.S. 5,254,801) in view of Goodman et al (U.S. 5,550,038), as stated on pages 13-14 of the last Office action for claims 61-63 and 66.

Claims 88, 92 and 96-98 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al (U.S. 5,426,041) in view of Dotson et al (U.S. 5,254,801), as stated on pages 14-15 of the last Office action.

Claims 60, 65, 67-68, 83-84, 89-91 and 99 (amended) and new claims 100, 105 and 107-108 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest the use of an oncogene 2 gene from *Agrobacterium* as a selectable marker for a second transgene conferring the claimed traits to plants transformed therewith, or the use of an auxin transport inhibitor in the culture medium for plant cells transformed with the oncogene 2 gene from *Agrobacterium*.

Claims 67-68, 83-84, 89-91 and 107-108 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 99 is allowed.

Applicants' arguments filed 17 June 2003 have been fully considered but they are not persuasive.

Applicants urge that the written description rejection is improper, given the knowledge by the skilled artisan of the structure of the proteins encoded by the claimed conditionally lethal genes, thus distinguishing the instant fact pattern from those of the cases cited by the Examiner.

The Examiner maintains that the structure of the proteins recited in claim 59 have not been disclosed by Applicants and do not appear to be known in the prior art. Furthermore, the claims are not limited to proteins of a particular sequence produced by a particular organism. Instead, the claims are broadly drawn to any gene from any source and any sequence encoding isopentyltransferases, methoxinine dehydrogenases, rhizobitoxine synthases, and phosphonate monoester hydrolases of any sequence. Given the cited cases' teaching that the disclosure of a single amino acid of known sequence was insufficient to describe a genus narrowly drawn to a gene encoding that protein, the much broader instant claims are clearly inadequately described.

Applicants urge that the enablement rejection is improper, given the contradictory position taken by the Examiner with respect to the art rejections, the failure of the references cited by the Examiner in the enablement rejection to support his position, and the assertions in the specification that any conditionally lethal gene would work.

With respect to the allegedly inconsistent rejections under 35 U.S.C. 112 and 35 U.S.C. 102 or 103, the Examiner maintains that the test for adequacy of a prior art disclosure to anticipate or render claims obvious is not the same test as that for

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adequacy of a patent application disclosure to support claims under 35 U.S.C. 112, as taught in *In re Hafner*, 161 USPQ 783, (CCPA 1969).

With respect to the references cited by the Examiner, the Examiner maintains that the references teach only limited instances of success, wherein the remaining instances of failure disclosed by each reference underscores the unpredictability inherent in the process. Given the claim breadth and lack of guidance in the instant specification addressing the problems set forth in the references, one skilled in the art would have been unable to practice Applicants' broadly claimed invention when relying only upon their specification. Applicants' mere assertions that any conditionally lethal gene would work are not probative in view of the scientific reasoning and published literature cited by the Examiner, as well as Applicants' own admission of the unique features of the iamH gene, as stated in the last Office action.

Applicants urge that the obviousness rejections are improper, given the failure of the cited references to singly teach all aspects of the claimed invention, and the lack of a motivation to combine their teachings. The Examiner maintains that motivation to combine the references' teachings rests within the references as well as the knowledge of the artisan of ordinary skill, as stated in the last Office action.

Furthermore, Applicants' evidence of unexpected results, namely successful selection of transformed plants via the use of a conditionally lethal marker gene, relies upon a single conditionally lethal gene, the iamH gene, and particularly claimed phenotypes of interest, including insect resistance, etc. In contrast, the claims are

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broadly drawn to any conditionally lethal gene (claim 59 and dependents) or any second gene of interest encoding any trait of interest (claim 88 and dependents).

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

August 24, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

